DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

November 13, 2001

WARNING LETTER NO. 2002-NOL-10

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. John W. Taylor, President
JOAMCA Chemical Products, Inc.
308 Distribution Drive
Madison, Mississippi 39110

Dear Mr. Taylor:

During October 1 – 9, 2001, an investigator of the U.S. Food and Drug Administration (FDA) conducted an inspection of your pharmaceutical, cosmetic, and medical device manufacturing facility, located at 308 Distribution Drive, Madison, Mississippi. The inspection was conducted to determine compliance with FDA's Current Good Manufacturing Practice (CGMP) for Finished Pharmaceuticals, Title 21, *Code of Federal Regulations*, Parts 210 and 211 and Cosmetics 21 CFR, Parts 700, 701, and 740. Our investigator documented deviations from the regulations that cause your finished pharmaceuticals, *SEPTI-DERM*, *PINK BLOSSOM*, *Kwik-San*, and *SANI-CLENS*, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The CGMP for finished pharmaceuticals deviations documented during the inspection include, but are not limited to, the following:

- Failure to establish a quality control unit;
- Failure to ensure that all employees involved in the manufacturing of products have the required and necessary training and experience;
- Failure to validate the cleaning of equipment used in drug product manufacturing process(es);
- Failure to qualify or validate the manufacturing equipment used to manufacture your drug product(s);

- Failure to maintain records of labeling and/or packaging receipt, sampling, testing, and acceptance/rejection;

- Failure to maintain a written record of equipment cleaning;

- Failure to maintain master and/or batch production records; and,

- Failure to establish or maintain standard written procedures for a quality control unit, change control, equipment cleaning and maintenance, master and batch production documents, component and container control, manufacturing process, batch yield calculation, control of labeling and packaging material, product warehousing and distribution, finished product testing, product stability program, product reserve, and complaint handling.

The above violations, as well as the Form FDA 483, List of Inspectional Observations, issued to you at the close of the inspection, are not intended to be an all-inclusive list of deficiencies at your manufacturing facility. It is your responsibility to assure that your facility is operating in compliance with applicable requirements and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that appropriate policies and procedures are implemented to prevent recurrence of the problems. Failure to promptly make corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Until such corrections have been made, Federal agencies will be advised of the issuance of this warning letter, so they may take this information into account when considering the award of contracts. Additionally, pending product or methods approval applications or export approval requests may not be approved until the above violations are corrected.

Our investigator also collected labeling for products that you manufacture. We are currently in the process of reviewing your product labeling and will address specific labeling issues in a follow-up letter.

You should be aware that drugs must comply with all existing labeling requirements of Section 502 of the Act and in 21 CFR, Part 201 and they must be manufactured by a registered facility and listed with FDA (21 CFR, Part 207). Cosmetics must comply with all existing labeling requirements of Section 601 of the Act and 21 CFR, Parts 700, 701, and 740.

You should also be aware that your product *KLEAN-n-SIMPLE* appears to be a Class I Medical Device due to labeling claims. Medical devices must comply with all existing labeling requirements of Section 502 of the Act and the Quality System Regulations, 21 CFR, Part 820, and they must be manufactured by a registered facility and listed with FDA (21 CFR, Part 807). You can find these forms on FDA's website at http://www.fda.gov/cdrh/reglistpage.html.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. Once corrective actions have been taken, forward to this office documentation necessary to verify that corrections have been

achieved. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time by which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483